



Alternative mechanisms to drive health outcomes through reimbursement

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Agenda

Context

- Increasing Healthcare costs...
- But resources are limited
- Reimbursement decisions are difficult for payers
- Europe moving from competitiveness to cost containment (since 2000)

How should we improve the cost-effectiveness of our health care system?

- Pure cost-containment is not the right answer
- New types of reimbursement agreements are necessary to answer the stakeholders needs

Introducing outcomes-based risk-sharing approach

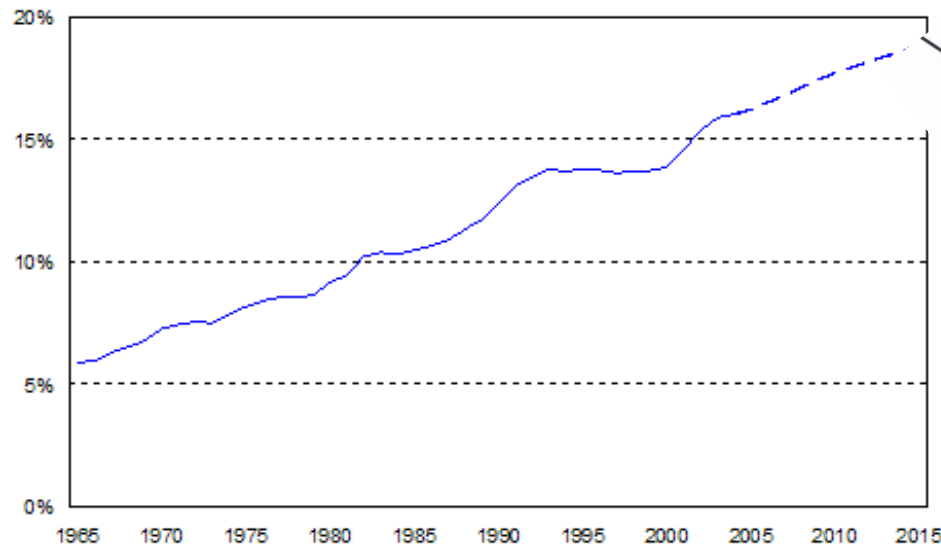
- Pros and cons of outcomes-based reimbursement

Conclusions



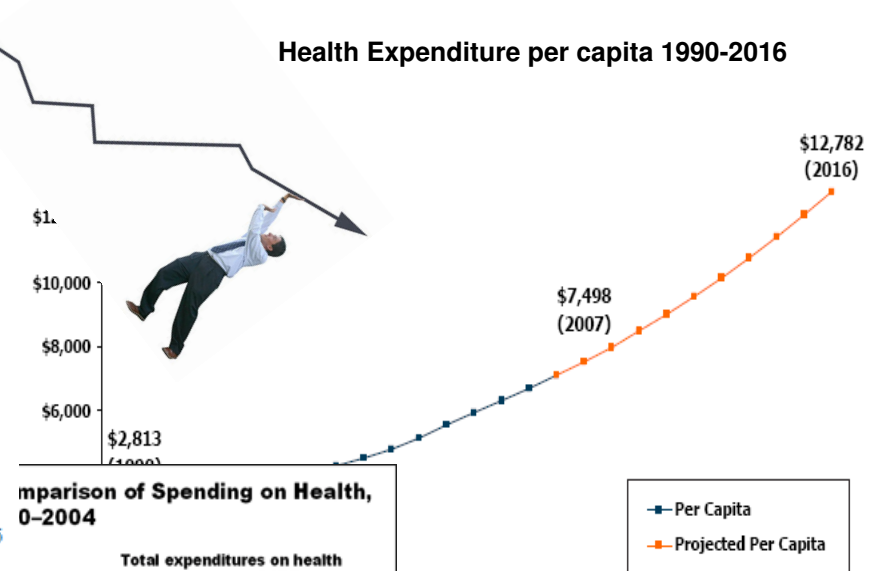
Health care costs are and will be increasing everywhere despite all the efforts done

Growth in National Health Expenditures as a Percentage of GDP

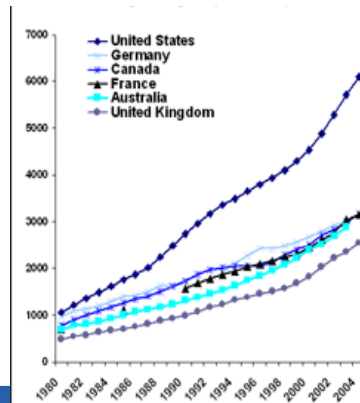


Source: Department of Health and Human Services (Centers for Medicare and Medicaid Services)

Health Expenditure per capita 1990-2016



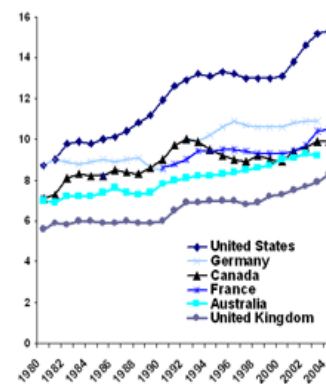
Comparison of Spending on Health, 1980-2004



Data: OECD Health Data 2005 and 2006.

Source: Commonwealth Fund National Scorecard on U.S. Health System Performance, 2006.

Total expenditures on health as percent of GDP



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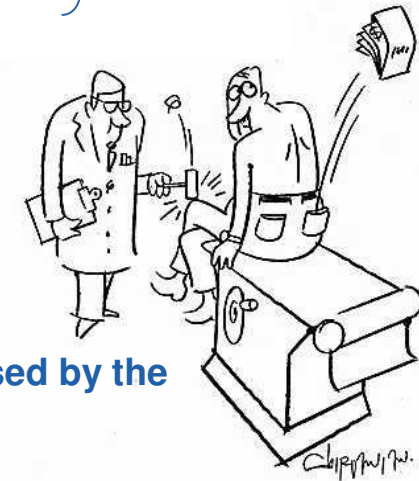


Health costs are and will be increasing worldwide

■ The main reasons behind that:

- Ageing population
- Patients are more healthcare concerned (diseases and therapies)
- Patients are more quality concerned
- More expensive to develop new technologies to improve health
- Poor diet and lack of exercise
- Abuses: smoking, alcohol consumption,...
- Non-compliance (e.g. statins)

But...better health contributes to economic growth

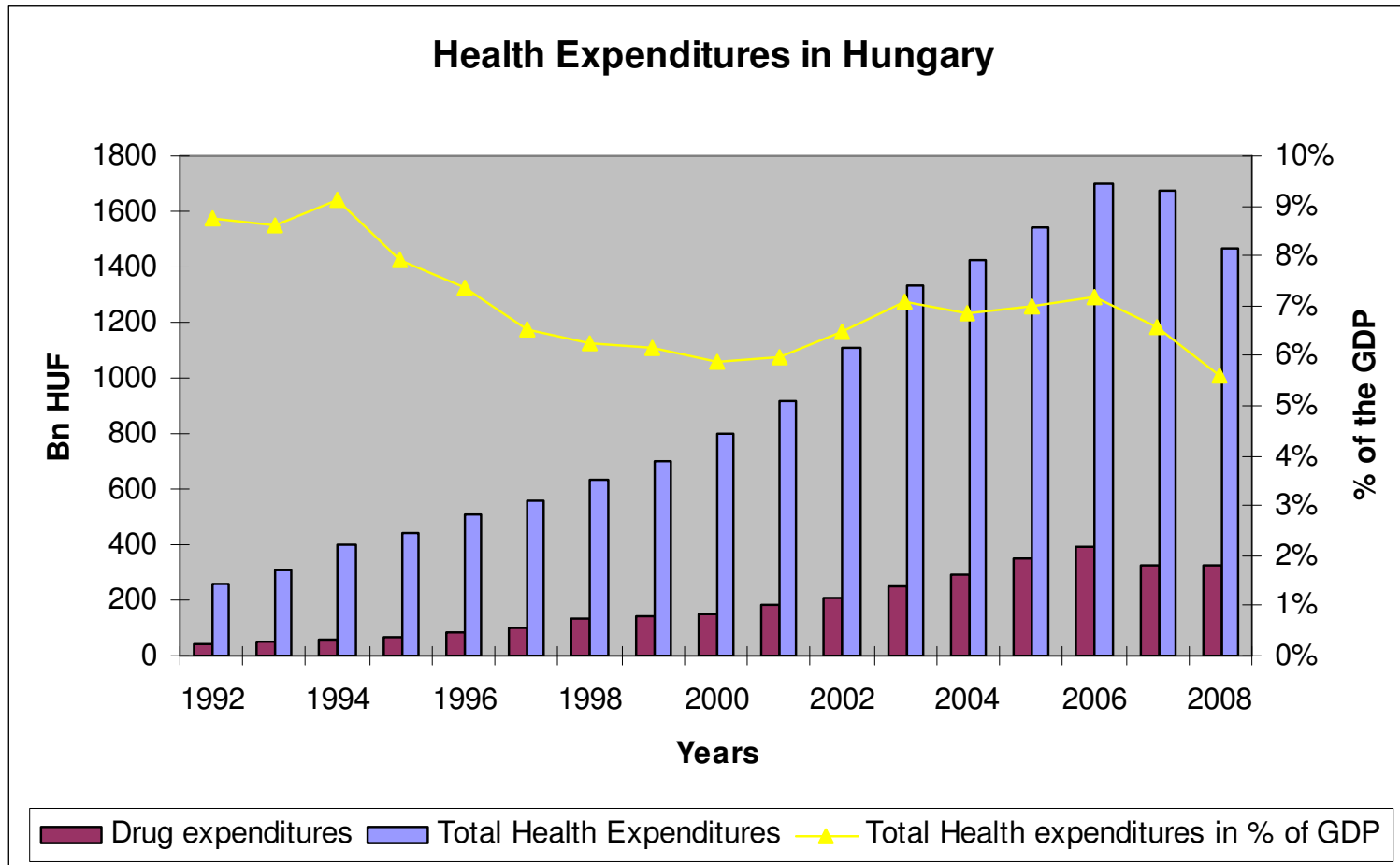


■ Current answers to that:

- Reduction of the cost of the drugs is one of the main levers used by the payers
- The answer is generally to shift costs to patients
- Cost-containment will continue

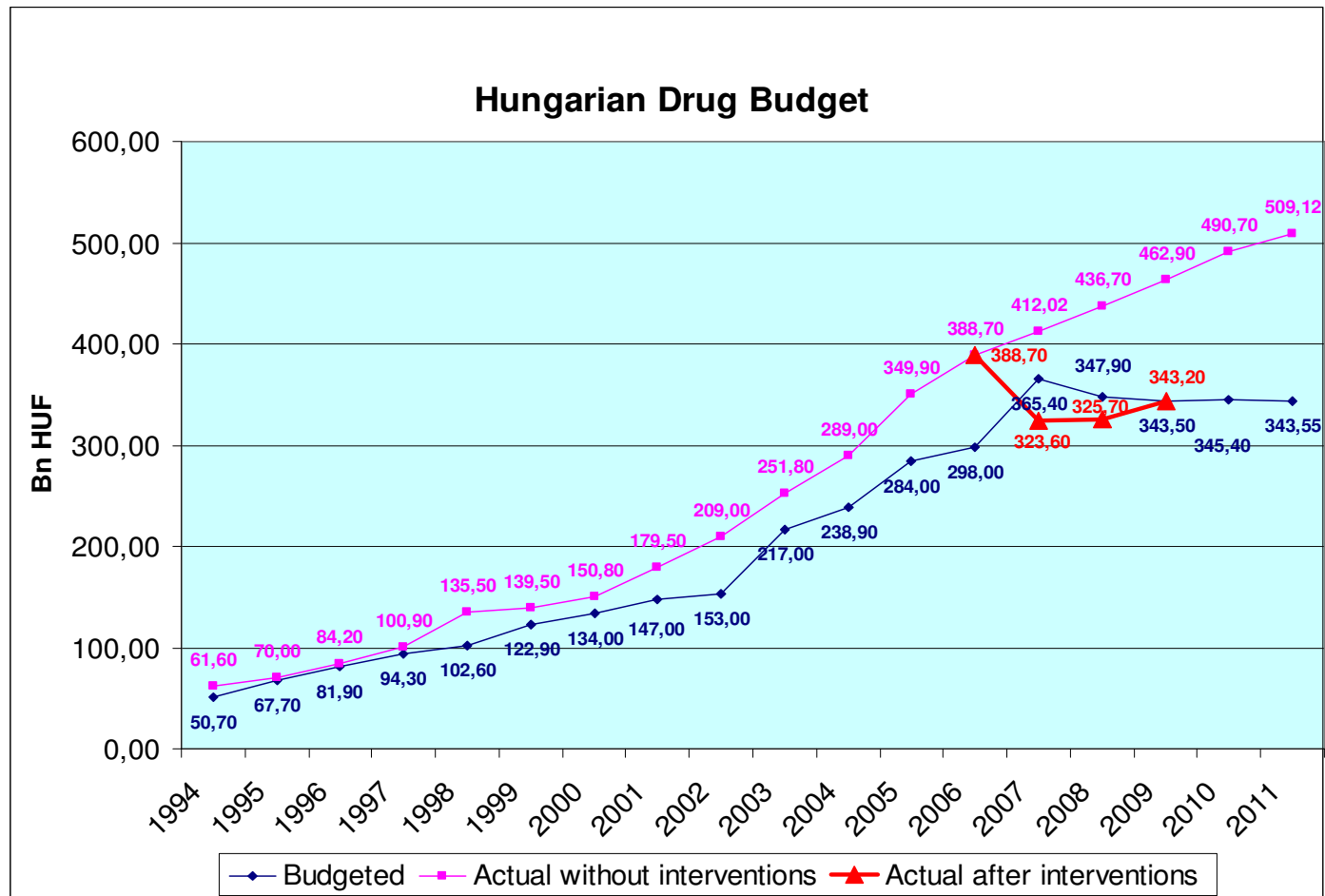


But in Hungary health expenditures show a decreasing trend





Drug budget is limited by cost containment interventions from payers side

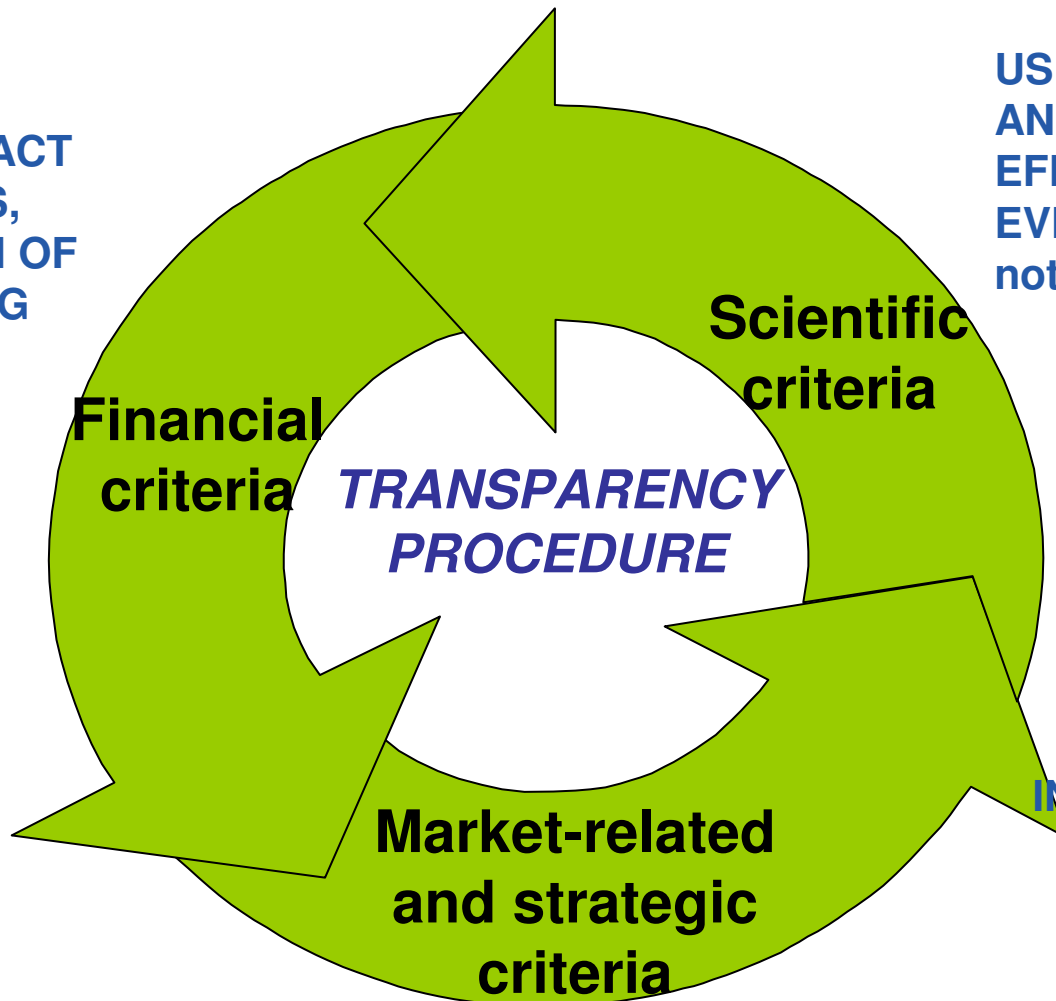


Source: www.oep.hu



Reimbursement decisions are complex from payers point of view

BUDGET IMPACT ESTIMATIONS, APPLICATION OF RISK-SHARING TECHNIQUES



USE OF CLINICAL AND COST-EFFECTIVENESS EVIDENCE (must but not enough)

PRICE NEGOTIATIONS, COMPETITIVENESS AND INNOVATIVENESS ISSUES

Source: www.oep.hu



The payers dilemma

- **Need to balance expectations of universal access to top level health care with limited budgets**
- **Need to maximise „public health outcome” for a given budget (cost-effectiveness)**
- **Need to make choices between therapeutic alternatives**



Shift of Mindset: From competitiveness to... cost containment

- ◆ **Lisbon Agenda (2000):** "To make Europe the most competitive and dynamic knowledge-based economy in the world"
- ◆ **G10 Medicines (2001-2002):** "Establish consensus between key stakeholders on ways to improve competitiveness of the pharmaceutical sector"
- ◆ **High Level Pharmaceutical Forum (2005-2008):** "To improve the performance of the pharmaceutical industry in terms of its competitiveness and contribution to social and public health objectives"
 - Information to patients
 - Pricing and reimbursement
 - Relative effectiveness
- ◆ **Joint Action on HTA: 2010-2012** „New decision making processes between industry, regulators, HTA bodies and payers deserve being tested to produce more evidence on the true value of technologies"
 - HTA objective is broader than costs containment
 - The objective is to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level.
 - To develop transparent governance tools

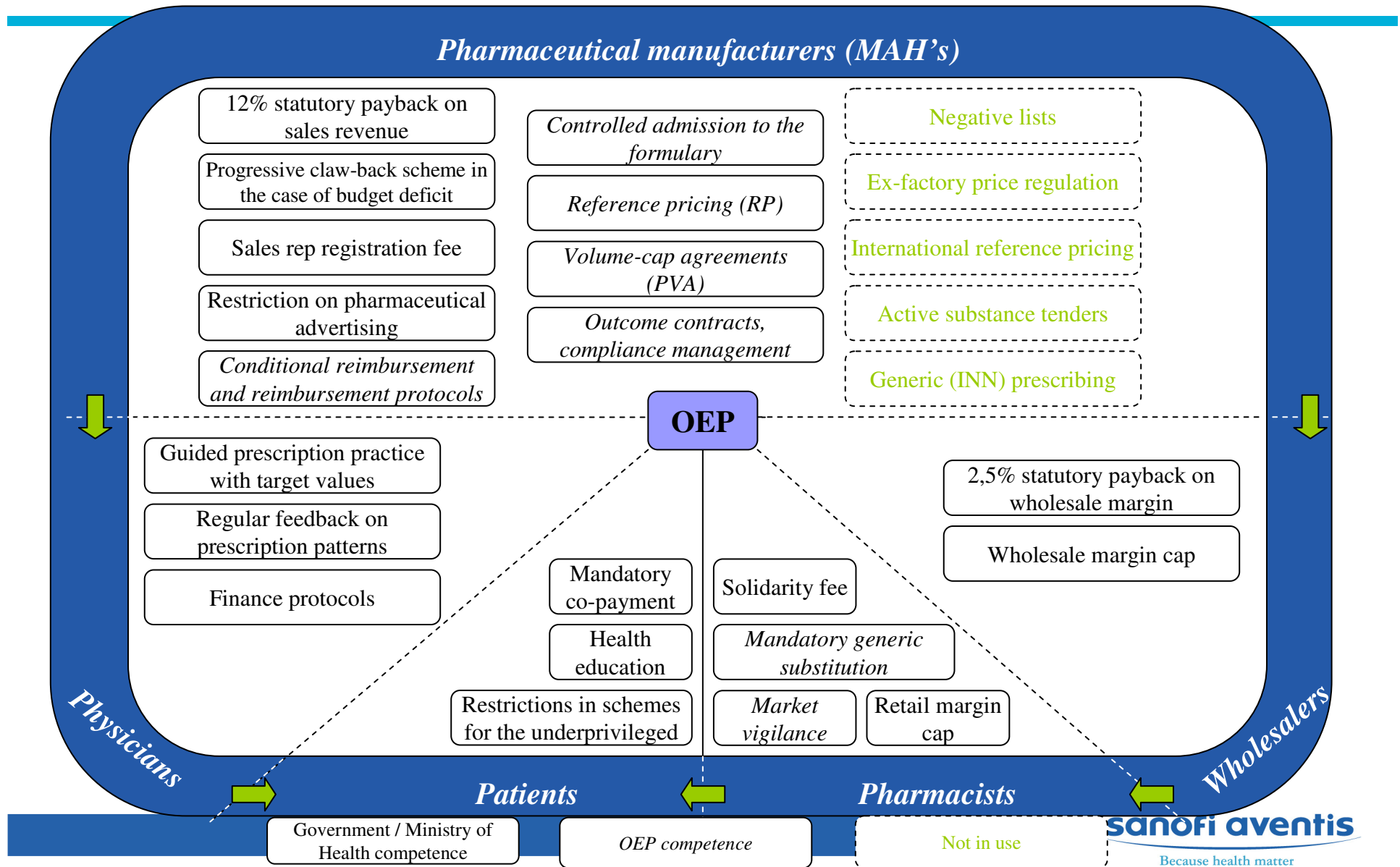


How should we improve the cost-effectiveness of our health care system?

- By introducing new, cost-effective medical technologies?
- By stimulating the use of existing cost-effective medical technologies?
 - Clinical and financial guideline development and dissemination (guided prescription practice)
 - Positive (or negative) financial incentives
 - De-reimbursement, negative lists for non-effective drugs
 - Indicator monitoring

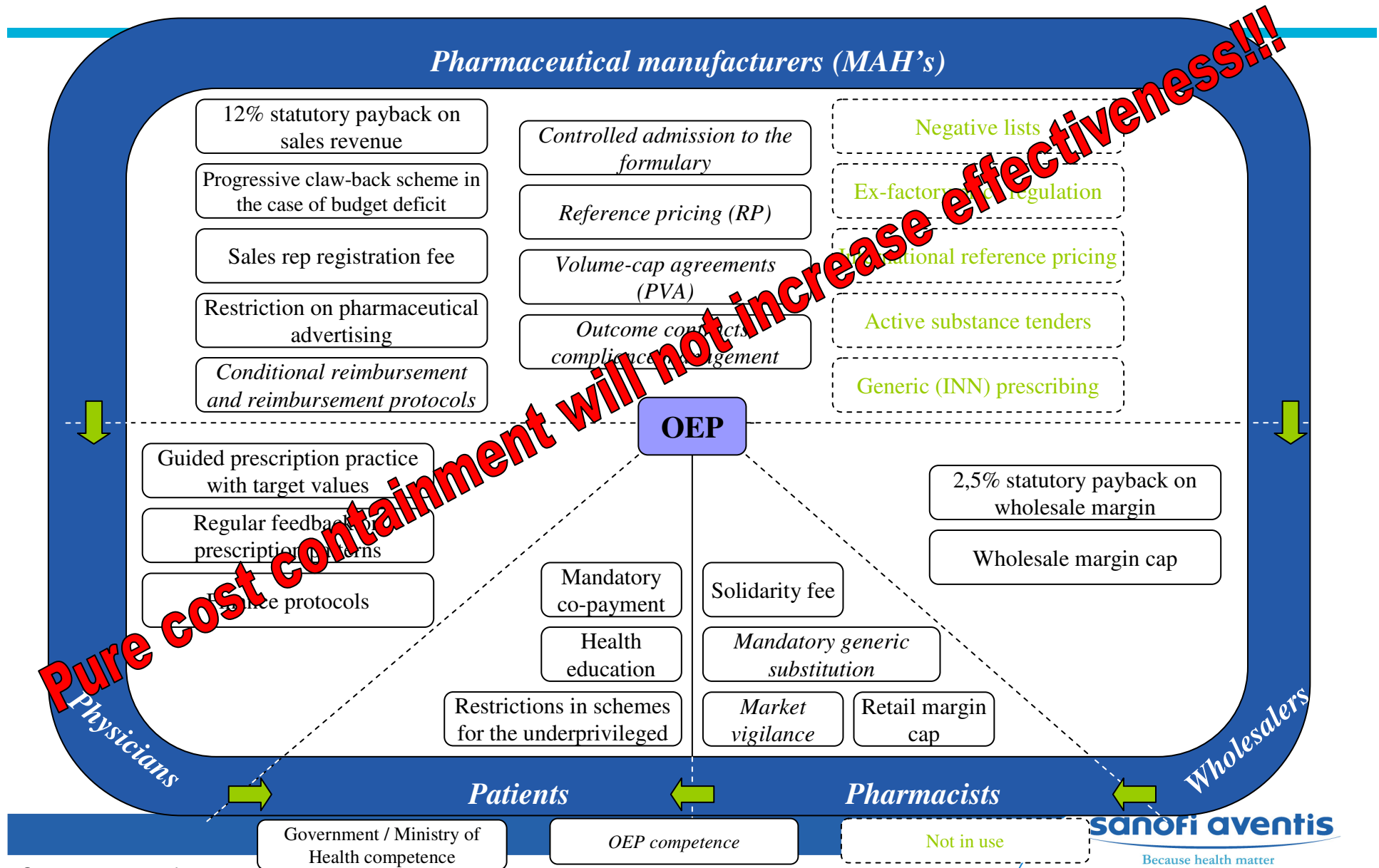


The cost containment toolkit in Hungary



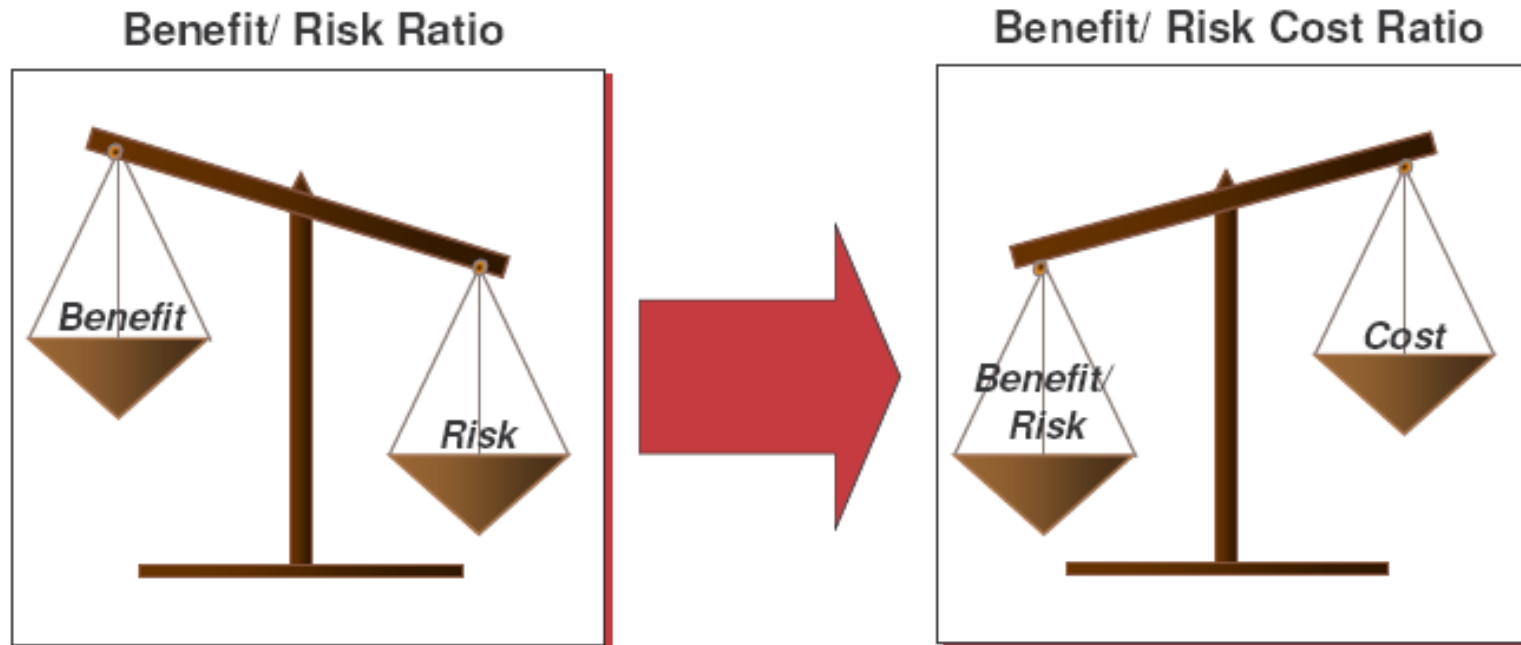


The cost containment toolkit in Hungary





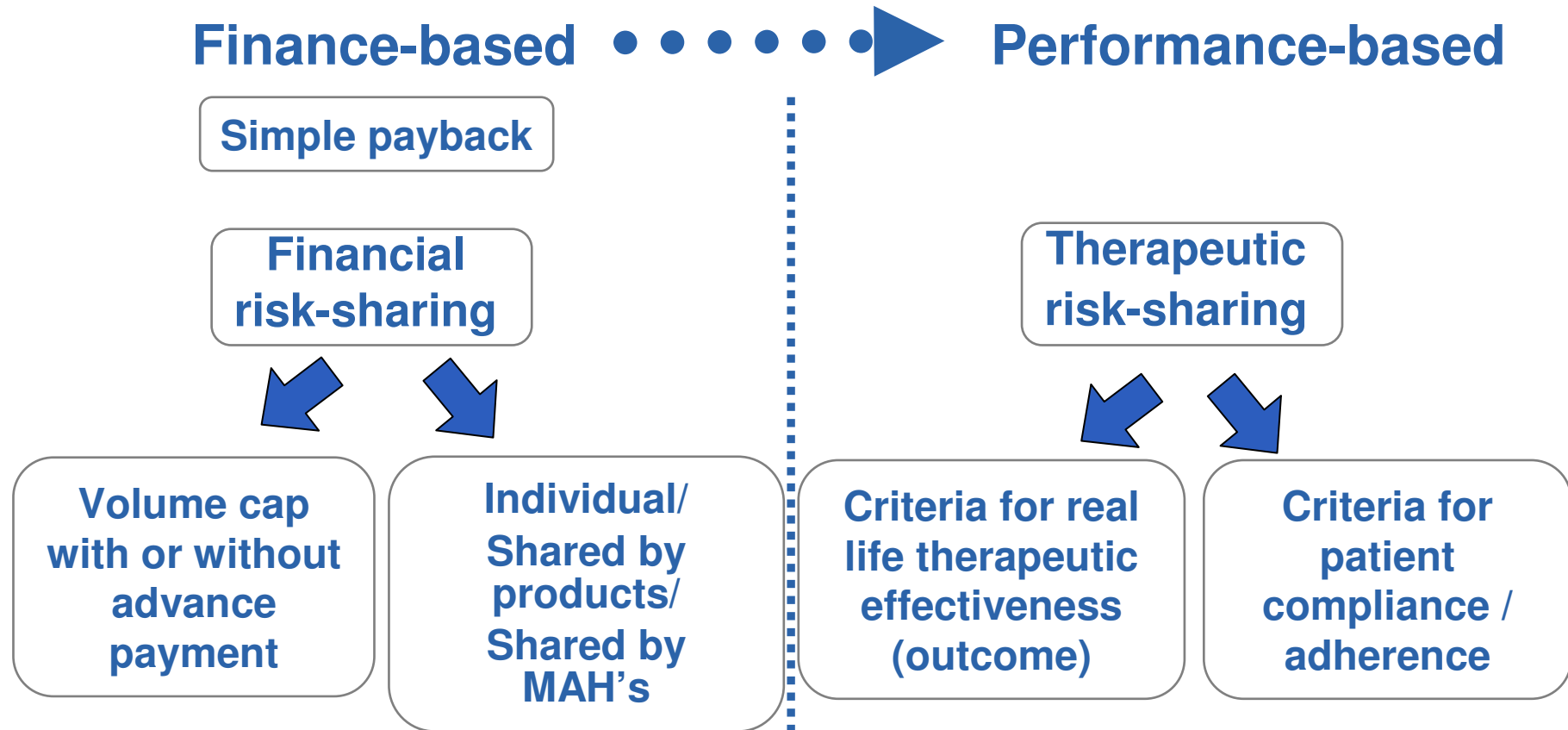
The Change in Paradigm: understanding of the medical needs AND the payers expectations



Value for money approach is always a comparative approach



New type of reimbursement agreements



Risk sharing agreements are becoming frequent in order to reduce uncertainty in the outcomes from new products

Market access agreements across Europe

Adopted outcomes-based agreements:

- UK
- Germany
- Italy
- Netherlands
- Portugal
- Belgium
- Sweden

Under consideration or non-formally exist :

- Almost all Central & Eastern European countries (e.g. Hungary)
- Ireland

Resisted to outcomes-based agreements (still finance-based):

- France
- Finland
- Spain



Advantages of outcomes-based risk-sharing agreements

- Enhanced value-based decision making on reimbursement
- Link payment to actual clinical performance
- Payers pay for the actual real life benefit
- Less wasted drugs on non-responders and non-compliance
- Fasten access to new innovative treatments
- Manufacturers with „strong” performance products can enjoy competitive advantages → no punishment for success
- Motivates the industry to become more innovative and develop better products
- Opportunity of partnership based cooperation between pharmaceuticals and payers



Issues with outcomes-based risk-sharing agreements

Methodological problems (standardisation)

- definition of effectiveness
- What are the right clinical outcome indicators to use
- What are the right comparators
- Inconsistent patient response rate

Objective clinical measures are not possible in many disease areas

Valid data are often missing therefore it is not easy to measure those indicators

Labour intensive to implement

Administrative problems with auditing/founding

- Responsibility of data collection and reporting is not clarified
- Data collection by a third-party monitor raises several legal and technical issues
- Extra administrative burden to all the stakeholders

Legal issues

- Patient rights and data protection
- Missing link between administrative and clinical outcome data

Costs can outweighs benefits.

Extra costs will drive further rise of pharmaceutical prices

Potential possibilities to abuse the system for all the stakeholders

Transparency and predictability are key

Patient involvement is critical

Rapid access



Hurdles which need to be taken in consideration

- **Cost containment remains**
 - Generification and class reference pricing impacts remain strong and quick
 - As payers, policy makers increasingly control the prescribing decision

- **Increasing needs for value based pricing on outcome data**

- **Risk sharing, conditional reimbursement**

- **Different and increased data needs**
 - Quality and access concerns of databases
 - More and timely direct comparative data
 - More data on targeted sub-population (genetic testing)
 - More specific local (real life) studies
 - Prospective Epidemiology
 - Registries Management
 - Evidence Based Medicine
 - Local HTA modelling

- **Adaptation is necessary**
 - HTA driven market access will be the backbone of companies through product life cycle, innovative MA techniques needed to develop
 - Closer collaboration with R&D (faster R&D = competitive advantage)
 - Disease management approach, patient focus



Conclusions

- Increasing need for value based pricing on real life effectiveness.
- Risk sharing agreements are becoming frequent in order to reduce uncertainty in the outcomes from new products
- Risk-sharing is not a magic tool, it can not be used everywhere and there are several unsolved problems in terms of defining clinical response and setting budget or utilisation caps, which can often upset the balance of cost-effectiveness thresholds.
- A key problem in the rise of risk-sharing agreements is that it has not been sufficiently legislated, nor adequately controlled or monitored. There are few guidelines on the specific criteria used to select when—and, perhaps more importantly, how—these agreements are applied.
- Transparency in decision making is needed from payers and manufacturers: agreements details should be made public
- Risk-sharing agreements could be interesting for pharmaceutical companies if such agreements guarantee that the new medicine will gain a faster access to the market. Otherwise it will be only an additional hurdle with additional expenses

A close-up photograph of a hand holding a large, smooth, blue heart. The heart is the central focus, with a soft glow around it. The hand is visible on the right side, with fingers gently gripping the heart. The background is dark and out of focus.

Thank you for your kind attention!

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